REMARKS

Claims 33-86 are pending in this application. Claims 33-72 and 81-86 have been withdrawn from consideration. Applicant has amended claim 73 to delete the term "prevention" and to substitute therefore the word "reduction." Applicant has also amended the title of the application accordingly. Support for these amendments may be found at least at Examples 4 and 6 in the present application, which both show that administration of the claimed composition resulted in a decrease in the Greene Score for menopausal symptoms which corresponds to treatment/amelioration of menopausal symptoms. Following entry of the present amendment, claims 73-80 are under examination.

Rejection of Claims 73-80 under 35 U.S.C. § 112, First Paragraph (Written Description)

The Office rejects claims 73-80 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Action at 2. Specifically, the Office states:

> The claims(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification does applicant disclose less than 10% biochanin A. Applicants disclose less than 10% of other isoflavones (page 9, lines 21-22) but do not disclose biochanin A **with particularity**. *Id.* (emphasis supplied).

The standard for written description is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention. *See* M.P.E.P. § 2163 at 2100-178. Disclosure "with particularity" is not required; in fact, the M.P.E.P. states that "[t]he subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." *Id.* at § 2163.02 at 2100-185. The inquiry is whether "the specification conveys with reasonable clarity" that applicant was in possession of the invention. *Id.* The specification provides at least "reasonable clarity"at page 9, lines 20-22, which reads:

> Formononetin or daidzein are preferably administered to a subject substantially unaccompanied by other isoflavones. By this is meant that any composition or preparations may contain minor amounts of other isoflavones, in the order of 10% (w/w) or less.

One of ordinary skill in the art would recognize that "other isoflavones" encompass biochanin A, regardless of whether it is disclosed "with particularity." *See, e.g.*, Specification at page 2, lines 26-30 ("A small sub-group of isoflavones (comprising daidzein, genistein, biochanin, and formononetin...) is distinguished by their ability to bind to estrogen receptors on animal (including human) cells. This is due to the close similarity of the steric structure of the diphenolic rings of isoflavones with the steroidal ring structure of estrogens such as estradiol, estrone and estriol.").

Thus, Applicant respectfully submits that the rejection of claims 73-80 under 35 U.S.C. § 112, first paragraph, should be withdrawn because the Applicant has described the invention with at least reasonable clarity.

Rejection of Claims 73-80 under 35 U.S.C. § 101

The Office rejects claims 73-80 under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. Action at 2. Specifically, the Office states that "[t]he claimed prevention of menopausal symptoms is not credible because applicant provides no standard by which to test prevention nor is evidence for prevention provided." *Id.*

Solely to facilitate prosecution and without acquiescing in the rejection, Applicant amends the claim to recite a "reduction of menopausal symptoms," rather than prevention. Thus, claim 73 would then read:

> Claim 73 (amended). A composition for the treatment or ~~prevention~~ reduction of menopausal symptoms in a post-menopausal woman, said composition comprising an effective amount of formononetin and biochanin A wherein the level of biochanin A is less than about 10% w/w of the isoflavone content, and wherein genistein, if present, is in the amount of less than about 5% w/w.

Applicant believes this amendment should address the Office's concerns, and respectfully requests that the rejection of claims 73-80 under 35 U.S.C. § 101 be withdrawn.

Rejection of Claims 73-80 under 35 U.S.C. § 112, First Paragraph (Enablement)

The Office rejects claims 73-80 under 35 U.S.C. § 112, first paragraph for lack of enablement. Action at 2. Specifically, the Office states that the specification is enabling for treatment, but "does not reasonably provide enablement for prevention." *Id.* The Office continues with:

> [t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Because the claimed invention is not credible, applicant is not enabled for the claimed method. *Id.*

Applicant submits that the amendment of claim 73, suggested above, should address this rejection, and respectfully requests that this rejection be withdrawn.

Double-Patenting Rejection of Claims 73-80

The Office maintains the nonstatutory obviousness-type double patenting rejection, stating that claims 73-80 are unpatentable over claim 11 of U.S. Patent No. 5,830,887 ("the '887 patent"). Action at 3. In focusing on the claimed percentages, the Office contends that claim 11 of the '887 patent "claims percentages of both formononetin and biochanin A without limit, that is, up to 100%, encompassing the instant claimed percentages." As to the amount of genistein, the Office asserts that it is optional and that "optimum suitable percentages may be obtained by routine experimentation." Action at 3-4.

Applicant respectfully traverses. Applicant has demonstrated that the claimed invention is far more than mere optimization of suitable percentages. First, the case law establishes that where the prior art has not recognized the "result-effective" capability of a particular invention

parameter, no expectation would exist that optimizing the parameter would successfully yield the desired improvement. *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977).

Here, the prior art had not recognized the "result-effective" capability of the optimal percentages of claim 73 "wherein the level of biochanin A is less than about 10% w/w of the isoflavone content, and wherein genistein, if present, is in the amount of less than about 5% w/w." Indeed, as set forth in the specification:

> Although it was previously thought that formononetin was almost immediately metabolised (demethylated) to daidzein upon the administration to a subject, the present inventors have found that formononetin persists in the blood stream for a considerable time (having a half life of generally about 20 hours).

Specification at page 9, lines 6-9. Indeed, Applicant provides this data in Example 5 at page 17.

In addition, Application provides data on the successful and significant reduction in the Greene Score by the administration of the claimed invention to post-menopausal women. *See* Examples 4 and 6. Thus, Applicant has demonstrated the persistence of formononetin and the reduction of menopausal symptoms after its administration.

Thus, no expectation existed in the prior art that optimizing the recited percentages would successfully treat or ameliorate the symptoms of menopause, as claimed in the instant application, and Applicant has shown the successful treatment/reduction of those symptoms. Therefore, the claimed invention is not an obvious variant of claim 11 of the '887 patent. Accordingly, it cannot constitute an improper time-wise extension, and, for at least this reason, Applicant respectfully requests the Office to withdraw the double-patenting rejection over claim 11 of the '887 patent.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests withdrawal of these rejections and timely allowance of the pending claims. Should the Examiner have remaining

questions or concerns regarding this application, Applicant requests that the Examiner contact the undersigned at 650-849-6611 to schedule an interview to discuss the application.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 11, 2006

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